PMD

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Publication Date 1-5-05

[Docket Nos. 2004D–0377 and 2004D–0378]

International Conference on Harmonisation; Draft Guidances on E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs and S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals; Availability; Reopening of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 18, 2005, the comment periods for the draft guidances entitled "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs" and "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals." The draft guidances were prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. FDA published notices of availability of the draft guidances in the **Federal Register** of September 13, 2004 (69 FR 55163 and 69 FR 55164, respectively). FDA is taking this action in response to requests to extend the comment periods for both draft guidances.

cd04163

NEC

DATES: Submit written or electronic comments on the draft guidances by February 18, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidances.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance entitled "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs": Douglas C. Throckmorton, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville MD, 20857, 301–594–5400.

Regarding the guidance entitled "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals": John Koerner, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–

5338.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 2004, FDA announced the availability of the following two draft guidances prepared under the auspices of the ICH:

- "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs" (69 FR 55163; Docket No. 2004D–0377) provides recommendations to sponsors concerning clinical studies to assess the potential of a new drug to cause cardiac arrhythmias, focusing on the assessment of changes in the QT/QTc interval on the electrocardiogram as a predictor of risk.

- "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals" (69 FR 55164; Docket No. 2004D–0378) describes a nonclinical testing strategy for assessing the potential of a test substance to delay ventricular repolarization and includes information concerning nonclinical assays and an integrated risk assessment.

Interested persons were given until December 13, 2004, to submit comments on the draft guidances.

On December 13, 2004, FDA received letters from Wyeth Pharmaceuticals requesting that the agency extend the comment periods for the draft guidances.

In response to these requests, FDA has decided to reopen the comment period on the draft guidances until February 18, 2005, to allow the public more time to review and comment on the contents.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances on or before February 18, 2005. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the corresponding docket number of the draft guidance as follows: Docket No. 2004D–0377 "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs" and Docket No. 2004D–0378 "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals." The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance documents at *http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm,* or *http://www.fda.gov/cber/publications.htm.*

Dated: December 28, 2004

December 28, 2004.

William K. Hubbard

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S